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| APPLICATION NO.  | FILING DATE          | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|----------------------|----------------------|---------------------|------------------|
| 10/624,192   | 07/21/2003           | Roger Blum           | 66741-029           | 7715             |
| MCDERMOTT, WILL & EMERY 4370 LA JOLLA VILLAGE DRIVE, SUITE 700 SAN DIEGO, CA 92122 |                      |                      | EXAMINER            |                  |
|  |                      |                      | MELLER, MICHAEL V   |                  |
|  |                      |                      | ART UNIT            | PAPER NUMBER     |
|  |                      |                      | 1655                |                  |
| ,  |                      |                      |                     | ·                |
| SHORTENED STATUTOR   | Y PERIOD OF RESPONSE | MAIL DATE            | DELIVERY MODE       |                  |
| 3 MO   | NTHS                 | 03/28/2007           | PAPER               |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|  | Application No.   | Applicant(s) |  |  |  |
|--|---|--------------|--|--|--|
|  | 10/624,192  | BLUM ET AL.  |  |  |  |
| ' Office Action Summary  | Examiner  | Art Unit     |  |  |  |
|  | Michael V. Meller   | 1655         |  |  |  |
| - The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |   |              |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |              |  |  |  |
| Status   |   | •            |  |  |  |
| <ol> <li>Responsive to communication(s) filed on 16 January 2007.</li> <li>This action is FINAL. 2b) This action is non-final.</li> <li>Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.</li> </ol>   |   |              |  |  |  |
| Disposition of Claims  |   |              |  |  |  |
| <ul> <li>4)  Claim(s) 1 and 12-28 is/are pending in the application.</li> <li>4a) Of the above claim(s) 1,14,16,17,19-22 and 25 is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 12, 13, 15, 18, 23, 24, 26-28 is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/or election requirement.</li> </ul>   |   |              |  |  |  |
| Application Papers   |   |              |  |  |  |
| 9) The specification is objected to by the Examiner.  10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |              |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |              |  |  |  |
| Priority under 35 U.S.C. § 119   |   |              |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.  |   |              |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date  | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P. 6) Other: | ite          |  |  |  |

## **DETAILED ACTION**

## Election/Restrictions

Applicant's election with traverse of Group II, claims 12, 13, 15-25 and Ponceau 4R as the only species of food color in the reply filed on 4/12/2006 is acknowledged. The traversal is on the ground(s) that the groups II and III are substantially the same since they both deal with enzymes. This is not found persuasive because they are materially distinct enzymes and a separate search is needed to be performed for a restriction enzyme versus a polymerase. Further, applicant is reminded of the extensive literature search involved in this art which is not co-extensive.

Thus, claims 1, 14, 16, 17, 18 (when it includes 14), 19, 20, 21, 22, 25 are withdrawn from further consideration since they are drawn to non-elected inventions.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 13, 15, 18, 23, 24, 26-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are written as methods with no steps and which do not conclude with what they state in the preamble. It is confusing as to what is being claimed. It would be clearer if applicant simply stated that the method of claim 12 for example read as, " A method for storing an enzyme comprising adding to the enzyme a food color, wherein the enzyme when stored shows no loss or less than 20 % loss of activity after prolonged storage."

Claim 13 still does not contain "when stored".

It would be clearer if applicant had something in the claims which made the steps clearer. There are two distinct steps of adding the ingredients and then storing, the claims do not reflect this fact.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12, 15, 23, 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Young (col. 1, lines 19-65, col. 2, lines 30-end).

Young teaches that papain and paprika are in a formulation used as a food additive. It is noted that the sensitivity of the enzyme (papain) is being protected from rapid loss of potency by chemical compounds added to the mixture. It is also noted that the mixture containing the enzyme (papain) retains activity for 12 months or longer.

Applicant argues that Young does not suggest adding an enzyme to a food color. On the contrary, Young is very clear that papain (the enzyme) and paprika (the food color) are together in the same composition, see Young, col. 2, lines 55-end. Young also states that the composition is a food additive which has a long shelf life when containing these components, see col. 1, lines 1-25. The shelf life is notes as 12 months or longer which clearly teaches the claimed invention. The comments concerning the "substantial potency" in col. 3, lines 1-10 of Young are not well taken since it is clear that this comment was made only with regard to a "specific preferred mixture" which does not take into account the whole patent which clearly teaches a shelf life of more than 12 months, see Young, col. 2, lines 25-40.

The less than 20 % loss of activity after prolonged storage is inherent to the claimed composition.

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## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12, 15, 23, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young (col. 1, lines 19-65, col. 2, lines 30-end).

Young teaches that papain and paprika are in a formulation used as a food additive. It is noted that the sensitivity of the enzyme (papain) is being protected from rapid loss of potency by chemical compounds added to the mixture. It is also noted that the mixture containing the enzyme (papain) retains activity for 12 months or longer.

In the event that it is seen that the period of storage is for up to one week or 6 months is not seen as reading on 12 months or longer it is herein noted that such a period of 12 months would easily read on such a time period since that time period includes times up to one week or 6 months which would include 12 months since 12 months is the greater of the two time periods of one week and 6 months.

The same arguments are offered as above thus the rebuttal is the same.

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Applicant argues that the skilled person would have been motivated to pick a specific food color to be in the composition but there is no requirement in the claims that this food color is the only food color or ingredient for that mater since applicants use "comprising" in the claims.

Claims 13 and 18 (when it does not include claim 14), 26-28 are allowable over the art.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael V. Meller Primary Examiner Art Unit 1655

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